QUESTIONS AND ANSWERS CONCERNING INGREDIENTS

1. Why are ingredients used?

ANSWER: Some ingredients aid in processing tobacco in the initial stages of cigarette manufacture. These ingredients increase the efficiency and yield of processing operations but remain in the final cigarette in minute quantities, if at all. Other ingredients are used as casing materials or humectants. Casing materials help to smooth the taste of cigarettes, while humectants keep the tobacco in cigarettes moist. Finally, many of the ingredients are used to give individual brands of cigarettes their distinctive flavor and aroma.

2. How long have ingredients been used in cigarettes?

ANSWER: Ingredients have always been used in cigarettes. Flavoring ingredients have been used in tobacco for as long as people have smoked. When Europeans first learned about smoking tobacco from the Indians, the tobacco they smoked was flavored with citrus peels and other natural spices and herbs. In the United States, the use of flavorings has been a common practice since colonial times. Most of the principal processing aids, casing materials, and humectants, for example, have not changed for decades. Many of the major flavors also have been in use for an extensive period. Other flavors have been added or eliminated from time to time as new

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products have been introduced or existing products have been reformulated in response to changing consumer preferences.

3. Why are so many ingredients used?

ANSWER: A relatively small number of ingredients, perhaps one-third of those on the lists submitted to HHS, are separately added directly to tobacco during cigarette manufacture. Twenty of those ingredients comprise approximately 99% of the total amount, by weight, of ingredients used in the industry. The other ingredients are used in smaller amounts, and most of the ingredients on the list submitted to HHS are used in extremely small quantities as part of flavor formulations. These formulations often include a number of ingredients, but typical industry-wide usage of most of these flavor components is under 10 pounds a year. This is in contrast with the over 900 million pounds of tobacco employed in cigarettes sold in the United States each year. The flavor formulations used by the companies change occasionally as new products are introduced or existing products are reformulated in response to consumer preferences.

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4. Why are so many ingredients used in American cigarettes, when many fewer ingredients are used in cigarettes made in many other countries?

ANSWER: Differences in the specific ingredients used in different countries reflect consumer preferences. Because of the use of ingredients, the American consumer has a wider choice of brands of cigarettes than are available in many foreign countries.

5. Are ingredients used in large amounts?

ANSWER: Ingredients do not comprise a significant portion of the final cigarette. Certain ingredients that serve as processing aids are used in volume during the early stages of manufacturing but are greatly reduced in the manufacturing process. Such processing aids remain in the final cigarette in minute quantities, if at all. A small number of casing materials, moisturizers, and major flavors account for the great bulk of ingredients actually in cigarettes.

A larger number of the ingredients are used as flavors, but these substances are in the final cigarette in minuscule amounts. Most of the ingredients are constituents of proprietary flavor mixtures, and usage of most of these ingredients by the entire industry is under 10 pounds per year. These ingredients will normally

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constitute less than one tenth of 1 percent by weight of the final product.

6. Haven't the cigarette manufacturers started using more and more ingredients to compensate for the reduction of tar and nicotine in cigarettes?

ANSWER: Most of the major ingredients used today have been used in cigarette manufacture for decades. It is true that, in recent years, a larger number of flavors have been made available for use in cigarettes -- in part because of an increased number of new brands and changes in existing brands. However, these flavoring ingredients are generally used in extremely small amounts and, in totality, represent less than one tenth of 1 percent by weight of the final cigarette. Overall, there has been no increase in the number of ingredients used in cigarettes or in the proportion of ingredients in the finished product.

7. Why hasn't the identity of ingredients been provided to the public before?

ANSWER: It is common for companies to guard specific product formulas. The flavors added to foods, for example, are treated as trade secrets and need not be disclosed on the labels of these products.

Because they contribute to the taste and appeal of individual brands, the identities of specific

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ingredients in cigarettes are also closely guarded trade secrets. Disclosure of the ingredients used in cigarette manufacture could reveal product formulas that required years of research to develop. The Federal Cigarette Labeling and Advertising Act recognizes the highly confidential nature of ingredients information by directing HHS to establish procedures to protect the confidentiality of the ingredients list.

Even though the ingredients are trade secrets, it should be noted that prior to the passage of Section 7(a) of the Federal Cigarette Labeling and Advertising Act in 1984, the industry had voluntarily cooperated with HHS on the question of ingredients. Under an agreement reached in 1982, the manufacturers had provided HHS with a list of commonly-used ingredients added to tobacco in the manufacture of cigarettes. The industry agreed then to consult with HHS as it addressed any questions about specific ingredients.

8. What role did the industry have in the preparation of HHS' ingredient report?

ANSWER: Since 1979 the industry has cooperated with HHS with respect to the ingredient issue. Prior to the requirement that annual lists be submitted, the industry voluntarily provided information to HHS. At all times

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the industry has informed HHS of its willingness to participate in a scientific review of ingredient usage.

Despite these repeated offers, the industry had no role in the HHS review of the ingredient lists. The industry was not consulted about the types of data that might be reviewed, and industry scientists who are perhaps the most knowledgeable persons about the use of ingredients in cigarettes were not called upon by HHS to provide information. Thus, HHS ignored a potential source of highly valuable information, and this resulted in numerous erroneous conclusions.

9. Don't consumers have the right to know what is in the products they buy?

ANSWER: The formulas of any number of consumer products are not treated as public information. These formulas often have great competitive value and require substantial time and expense to develop. The law therefore allows them to be treated as trade secrets. For example, the flavorings used in hundreds of foods and in fragrances are treated as trade secrets.

10. Why aren't the ingredients used in cigarettes listed on the package?

ANSWER: The identities of specific ingredients used in a particular brand of cigarettes are important trade

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secrets. The taste of a specific brand may take years of time and millions of dollars to develop, and the law recognizes that such valuable information is entitled to confidential treatment. For example, the flavors used in hundreds of foods are treated as trade secrets.

11. The list of additives which has been supplied to HHS consists of those substances which are currently added to cigarettes. Have any substances been phased out of use in cigarettes since the submission of annual lists began?

ANSWER: Like almost all consumer products, from frozen foods to breads or soft drinks, cigarettes undergo constant change as new brands are introduced and old brands are modified or phased out. Modifications in cigarette formulations may be required to compensate for changes in tobacco caused by variations in weather patterns, environmental conditions or agricultural practices. Changes are also made to meet consumer demand for palatable low "tar" cigarettes. However, most of the modifications in the composition of cigarettes affect flavor constituents used in extremely small quantities. For many of these ingredients, the amount used annually is less than ten pounds for the entire industry. The major ingredients change less often, and many of them have been used for years.

The cigarette manufacturers have complied with the procedures adopted by HHS by submitting an initial

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list on April 2, 1986 and annual lists each subsequent December. Any changes in the ingredients used in cigarettes will be reflected in the lists submitted annually.

12. Are there any substances currently added to cigarettes sold only in other markets, particularly Third World markets, which are not used in cigarettes sold in the United States?

ANSWER: The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients used in cigarettes sold in the United States, and we have not compiled information on cigarettes sold in other countries. However, a number of other countries regulate the use of ingredients in cigarettes, and the companies comply with these regulations wherever they exist.

13. Are ingredients added to filters, and if so, what ingredients are added and what tests have been done to evaluate their safety?

ANSWER: The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients added to the tobacco used in cigarettes sold in the United States. We have not compiled information on ingredients which might be added to other portions of the cigarette.

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14. Are the ingredients used in cigarettes harmful?

ANSWER: There is no legitimate basis for the conclusion that the addition to cigarettes of the ingredients on the list is harmful to smokers. Virtually all substances are toxic at very high levels, but there is no evidence that the small quantities of ingredients used in cigarettes are harmful.

15. What evidence is there that the ingredients are not harmful?

ANSWER: Most of the ingredients are approved for use in foods by the Food and Drug Administration and are included in other lists of approved food, drug, and cosmetic ingredients in the United States and other countries. The inclusion of ingredients on these lists generally reflects a careful review of available data by scientists. Many of the ingredients are also included on approved lists of tobacco additives in Great Britain and Germany. These lists were prepared by scientists familiar with the uses of ingredients and information on their safety.

The companies have likewise reviewed available scientific evidence about the ingredients on the list. This includes test data found in the published scientific literature, as well as the results of unpublished research, on many of the ingredients. The available data

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show that the ingredients used in foods and other articles for human consumption are not harmful. The data also indicate that the presence of ingredients in cigarettes does not materially affect the chemical composition of cigarette smoke.

16. Are there any substances which have historically been used as additives in cigarettes that are now regarded as hazardous?

ANSWER: In the past, the cigarette manufacturers have reviewed the questions that have arisen concerning ingredients. The companies do not believe that the addition to cigarettes of ingredients formerly or currently used has been harmful to smokers.

17. Why is there any reason to think that an ingredient is not harmful just because it has been used for a long period of time?

ANSWER: Longstanding use alone may not establish that an ingredient is not harmful. However, most of the major ingredients used in large quantities in the production of cigarettes are either foods or are approved for use in foods or in the manufacture of food products. For these major ingredients, test data are available concerning both their food and tobacco applications. Despite extensive use, no evidence has been presented to

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establish that the addition of these ingredients to cigarettes is harmful to smokers.

18. What effect do ingredients have on non-smokers exposed to cigarette smoke?

ANSWER: The companies believe that the addition to cigarettes of the ingredients on the list is not harmful to smokers. The companies likewise do not believe that the addition of ingredients to cigarettes is harmful to non-smokers who may be exposed to cigarette smoke.

19. Have each of the ingredients been tested to ensure that they are not harmful?

ANSWER: Since most of the ingredients are approved for use in foods, testing to determine their toxicity has been conducted. The tobacco companies have conducted additional testing on many ingredients and mixtures of ingredients which attempt to address the conditions encountered during cigarette smoking. All of the major cigarette ingredients have undergone extensive testing and many minor ingredients have been tested. Industry has conducted appropriate tests to supplement the great body of evidence on ingredients.

20. What kinds of tests have been done on ingredients?

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ANSWER: The need for testing, and the types of tests to be conducted, depend on a range of factors. There is no accepted testing methodology for evaluating ingredients. Nonetheless, depending on the circumstances, the research conducted includes acute and chronic toxicity studies, and various in vitro studies. In addition, tests have been done to determine whether the presence of ingredients in cigarettes affects the chemical composition of tobacco smoke.

21. The GRAS list and others list many of these ingredients as fit for human consumption, but fail to address the issue of potential dangers posed by the burning of these substances. What research has the industry done concerning the effects of pyrolysis on these substances?

ANSWER: This question is based on a misunderstanding of what happens to ingredients. Many of the ingredients are not pyrolyzed in cigarettes. Their boiling points are well below the temperature of a burning cigarette, and instead of burning they are transferred intact into cigarette smoke. This is by design, so that the flavor of the ingredient is imparted to the smoker. Because the ingredients are not burned, data related to their use in foods is helpful in evaluating their effects when used in cigarettes. Moreover, many foods and food additives approved by FDA are subject to elevated temperatures

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during food processing and common forms of cooking, such as frying, baking and broiling.

For many other ingredients, overall usage levels indicate that pyrolysis data is of low priority. Only twenty or so ingredients account for approximately 99% of the total amount of ingredients used. The rest are used in smaller quantities. Most of the ingredients are used as part of flavor mixtures, and total industry usage of most of these ingredients is less than ten pounds a year. Moreover, a number of the major ingredients are processing aids that remain in the final cigarette in minute quantities, if at all. For ingredients present in cigarettes in minimal quantities, the absence of significant exposure potential limits the need for pyrolysis testing.

Finally, tests have been done using research cigarettes containing much larger amounts of added ingredients than are used in commercial cigarettes. The smoke and/or the condensate from these cigarettes have been evaluated through animal and other tests that have been used in scientific research to investigate the biological effects of cigarette smoke. The tests have not demonstrated that the addition to cigarettes of the ingredients on the list is harmful to smokers.

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22. Why haven't pyrolysis tests been run for all ingredients being used?

ANSWER: Many ingredients used in cigarettes are not pyrolyzed. They have relatively low boiling points, below the temperature of a burning cigarette, and they are transferred intact from the cigarette to the tobacco smoke. In fact, flavors are often selected for their low boiling points, which assure that their flavoring properties are imparted to cigarette smoke. Hence, for these ingredients, pyrolysis tests are not relevant.

Pyrolysis testing on other types of ingredients is not called for in view of the manner in which they are used. Processing aids, for example, appear in the final cigarette in minute quantities, if at all. In addition, a large number of ingredients used as components of flavor mixtures are likewise found in cigarettes in minuscule quantities.

23. Are there any studies that examine the effects of the ingredients when they have been inhaled?

ANSWER: Such studies have been done on some ingredients. The companies believe that these studies have not shown that the addition to cigarettes of the ingredients tested is harmful to smokers.

24. What value is any test other than a pyrolysis or inhalation test?

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ANSWER: Where inhalation studies are not available or possible, it is necessary and customary, in regulatory agencies and the scientific community, to rely upon ingestion studies. For cigarette ingredients, inhalation or pyrolysis tests may often provide the most directly relevant data, but other tests can be valuable.

25. Are you aware of any adverse health data generated either by the companies or available in the published literature?

ANSWER: Based on their review of available data and information, the companies do not believe that the addition of the ingredients to cigarettes is harmful to smokers.

26. Is more testing of ingredients planned?

ANSWER: The testing of ingredients has been conducted by individual companies on their own initiative. Companies will continue to conduct tests where they believe such tests are warranted.

27. You have noted that various bodies such as FEMA or FDA have approved the ingredients for use in foods. Why does that matter, since those organizations have not burned the ingredients?

ANSWER: The inclusion of the ingredients on lists of substances approved for food use by FEMA or FDA indicates that data have been reviewed by scientists who have

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concluded that the ingredient is suitable for human consumption. It may be appropriate to consider other types of data as well, but FDA's and FEMA's approval of the ingredients should receive considerable weight in evaluating exposure to the same substances through other routes. It should be noted that many foods and food additives approved by FDA are subject to high temperatures during food processing and common forms of cooking, such as frying, baking and broiling.

28. Isn't it true that the committees which compiled the list of approved tobacco additives in Great Britain and in Germany did not have much information available to them about specific ingredients, but rather conducted a cursory examination?

ANSWER: These committees included independent scientists and government representatives. In developing a list of approved substances, they examined the evidence they believed necessary to make an adequate evaluation, and concluded that the ingredients were suitable for use in cigarette manufacture. In some cases, the committees had available to them a large body of evidence, including test results. In other instances, a smaller amount of evidence may have been available, particularly for substances typically used only in small quantities. Nevertheless, the review was independent and thorough.

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29. What are the large-volume ingredients, why are they used, and what is known about their health effects?

ANSWER: While comment on the identity of any individual ingredient would be inappropriate, they generally have been used in cigarettes for decades and are extensively used in foods. Most of these ingredients serve as casing materials, humectants, or processing aids. Processing aids will remain in the final cigarettes only in minute quantities, if at all. Casing materials assist in producing a cigarette with a satisfactory taste and texture, and humectants serve to retain the moisture in cigarettes. Certain ingredients used as flavors in the more popular brands of cigarettes may also be used in larger quantities on an annual basis.

A variety of tests have been done to evaluate the health effects of the major ingredients. These include tests by the companies, as well as other work reflected in the published literature. Based on the available information, the companies do not believe that the addition to cigarettes of the ingredients on the list is harmful to smokers.

30. How many known carcinogens are on the list of ingredients which was submitted to HHS?

ANSWER: None of the substances on the list are considered potential human carcinogens by HHS, the

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International Agency for Research on Cancer (IARC), or other recognized organizations which evaluate the carcinogenic potential of substances.

31. Are natural extracts harmful?

ANSWER: Natural extracts are used in a multitude of foods, drugs, and other products. HHS' criticism of their use in cigarettes is contrary to FDA's approval of such extracts for use in many other products. Virtually all substances, natural and synthetic, are toxic at very high levels, but there is no evidence that the small quantities of ingredients used in cigarettes are harmful.

32. Have the cigarette manufacturers ever used cloves, eugenol, or coumarin in their cigarettes?

ANSWER: Because specific ingredients are important trade secrets, the industry will not comment on whether these substances are being or have been used.

[Note -- this response will be used for all questions about specific ingredients.]

33. The HHS report indicates that ingredients such as cloves, eugenol and coumarin are used. Is the industry really using these compounds?

ANSWER: While we cannot comment on the specific ingredients used by United States manufacturers, it is

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important to note that HHS received submissions not only from Covington and Burling on behalf of the six major United States manufacturers, but from other manufacturers and importers of cigarettes as well.

34. A government scientist referred in an article a few years ago in Mother Jones magazine to an unidentifiable "Compound X" which he had discovered in a cigarette. Does this compound really exist, and if so, what does the industry know about it?

ANSWER: The companies have no information about the specific compound which is referred to but not identified in the Mother Jones article.

35. Why is the industry using Covington and Burling as its spokesperson?

ANSWER: The Federal Cigarette Labeling and Advertising Act allows companies jointly to designate an agent to prepare a combined list of ingredients. This is designed to protect the trade secret status of each company's ingredient information. Covington and Burling assisted the industry in earlier discussions with HHS concerning ingredients, and the companies have asked Covington and Burling to continue that representation.

36. Isn't it true that you really do not know what effect these ingredients are having on the health of smokers?

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ANSWER: The companies have reviewed the scientific literature on ingredients and, where appropriate, they have conducted their own tests to obtain additional scientific evidence. The companies believe that the addition to cigarettes of the ingredients on the list is not harmful to smokers.

37. Don't ingredients simply add to the danger presented by cigarettes?

ANSWER: The industry does not believe that it has been established that cigarette smoking causes disease in smokers, or that the addition to cigarettes of the ingredients is harmful to smokers. Most cigarette ingredients are foods or approved for use in food by FDA. The companies have reviewed the extensive scientific literature on ingredients, conducted their own tests where appropriate and concluded that the addition of the ingredients on the list to cigarettes is not harmful.

38. Shouldn't the United States have a list of approved ingredients, as in Great Britain or West Germany?

ANSWER: The Federal Cigarette Labeling and Advertising Act provides HHS with ample authority to review the ingredients in use. Current regulation of ingredients is flexible, in that it permits product innovation and still

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allows HHS to monitor the use of ingredients. We do not believe that any change in this approach is necessary.

39. In light of the nonchalant way in which the cigarette industry has used untested additives in billions of cigarettes every year, isn't it time that ingredients were brought under the aegis of the FDA?

ANSWER: The industry has not acted in a nonchalant way. Indeed, quite the opposite is true. Ingredients are carefully selected and screened prior to use. Moreover, as the recently released report by HHS shows, HHS has the necessary authority to review the use of ingredients. We see no reason to create an additional review mechanism.

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